REMARKS

By the present amendment, applicants have canceled Claims 26-29, and added new Claims 37-39. Support for new Claim 37 is found in cancelled Claims 26 and 27. Support for new Claim 38 is found in cancelled Claim 28. Support for new Claim 39 is found in cancelled Claim 29. Therefore, the claims remaining for consideration by the Examiner are Claims 30-39.

The Examiner has rejected Claims 26-29 under 35 U.S.C. 102(b) as being anticipated by JP 03/031286. In the alternative, the Examiner has rejected Claims 26 and 29 under 35 U.S.C. 102(b) as being anticipated by JP 60-004189. The Examiner states that JP 03/031286 or JP 60-004189 would implicitly disclose a crystalline form of N-formyl-cefpodoxime proxetil.

JP 03/031286 describes a process to prepare (RS)-cefpodoxime proxetil by eliminating the formyl group of N-formyl-cefpodoxime proxetil. The process involves treating N-formyl-cefpodoxime proxetil with methanesulfonic acid or trifluoromethanesulfonic acid. However, JP 03/031286 does not describe any method for preparing the N-formyl-cefpodoxime proxetil except to state on page 2, second paragraph of the translation, that the compound of formula (2) i.e. cefpodoxime proxetil, may be obtained by elimination of a formyl group from the compound of formula (1) i.e. N-formyl-cefpodoxime proxetil, with reference to JP 60-67483. Applicants note that JP 60-67483 relates to a communication error preventing device for a drum peripheral unit. Applicants have attached an English language translation of the abstract for JP 60-67483 for the Examiner's review.

Applicants believe that JP 03/031286 meant to refer to JP 60-004189 which describes a process for preparing ß-lactam compounds, specifically N-formyl-cefpodoxime proxetil. In Example 1 of JP 60-004189, Isomer A of N-formyl-cefpodoxime proxetil is prepared by reacting 1-(isopropyloxycarbonyloxy)ethyl-7-amino-3-methoxymethyl-3-cephem-4-carboxylate-p-toluenesulfonate (Isomer A) with 2-(2-formylaminothiazol-4-yl)- (Z)-2-methoxyiminoacetic acid in the presence of phosphorus oxychloride. The obtained residue was washed, collected by filtration and characterized by ^{1}H-NMR spectroscopy.

In Example 2 of JP 60-004189, Isomer B of N-formyl-cefpodoxime proxetil is prepared by reacting 1-(isopropyloxycarbonyloxy)ethyl-7-amino-3-methoxymethyl-3-cephem-4-carboxylate hydrochloride (Isomer B) with 2-(2-formylaminothiazol-4-yl)-(Z)-2-methoxyiminoacetic acid in the presence of phosphorus oxychloride. The obtained residue was washed, collected by filtration and characterized by ^{1}H-NMR spectroscopy.

In view of the disclosure of JP 60-004189, applicants have submitted herewith a Declaration under 37 CFR § 1.132 by Dr. Johannes Ludescher. A copy of the Rule 132 Declaration is attached hereto for review by the Examiner. In the Rule 132 Declaration, Dr. Ludescher prepared N-formyl-cefpodoxime proxetil by two methods. In the first method, Dr. Ludescher prepared Isomer A and Isomer B of N-formyl-cefpodoxime proxetil according to Examples 1 and 2, respectively, of JP 60-004189, and combined Isomer A and Isomer B in a

diastereoisomeric ratio of 0.5. An X-ray powder diffraction pattern was determined for the N-formyl-cefpodoxime proxetil which was prepared according to JP 60-004189, and is set forth as Figure 1 in the Rule 132 Declaration.

In the second method, Dr. Ludescher prepared N-formyl-cefpodoxime proxetil according to applicants' Examples 1 and 2(a), on page 9 of applicants' specification. An X-ray powder diffraction pattern was determined for the N-formyl-cefpodoxime proxetil which was prepared according to applicants' process, as claimed, and is set forth as Figure 2 in the Rule 132 Declaration.

As stated in the Rule 132 Declaration, it is clear that the X-ray powder diffraction pattern of N-formyl-cefpodoxime proxetil as shown in Figure 1 does not have any distinct peaks. Thus, the racemic mixture of N-formyl-cefpodoxime proxetil that was described as the starting material in Example 1 of JP-3-31286 which was prepared according to JP 60-004189 is amorphous. In contrast, the X-ray powder diffraction pattern of N-formyl-cefpodoxime proxetil as shown in Figure 2 shows clear distinct peaks indicating that N-formyl-cefpodoxime proxetil prepared according to Applicants' Example 2(a) is crystalline. Thus, neither JP 03/031286 nor JP 60-004189 disclose a crystalline diastereoisomeric mixture of N-formyl-cefpodoxime proxetil, as claimed by applicants.

In view of the above experimental results set forth in applicants' Rule 132 Declaration and arguments, it should be unambiguously clear that neither JP 03/031286 nor JP 60-67483, evaluated alone or in combination, suggest applicants' crystalline diastereoisomeric mixture of N-formyl-cefpodoxime proxetil, as claimed.

Respectfully submitted,

Novartis
Corporate Intellectual Property
One Health Plaza, Building 104
East Hanover, NJ 07936-1080
(862) 778-7945

John D. Thallemer
Attorney for Applicants
Reg. No. 34,940

Date: November 29, 2004